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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,770	11/08/1999	TAKUO YAMAMOTO	YAMAMOTO=16A	5666
1444	7590	06/29/2005	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			FRONDA, CHRISTIAN L	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/435,770	YAMAMOTO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christian L. Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 June 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 59-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 59 and 65-70 is/are rejected.
- 7) Claim(s) 60-64 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 08 November 1999 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 06/13/2005 has been entered.
2. Claims 59-70 are pending and under consideration in this Office Action.
3. The rejection of claims 9 and 13 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is moot in view of applicants' cancellation of these claims. This rejection has been withdrawn.

### ***Claim Rejections - 35 U.S.C. § 112, 1st Paragraph***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 59 and 65-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a purified non-reducing saccharide-forming enzyme which forms a non-reducing saccharide having a trehalose structure as an end unit from a reducing partial starch hydrolysate and comprises an amino acid sequence as set forth in SEQ ID NO:1; does not reasonably provide enablement for such an enzyme comprising an amino acid sequence that is at least 80% identical to SEQ ID NO: 1 which forms a non-reducing saccharide having a trehalose structure as an end unit from a reducing partial starch hydrolysate, where such enzyme is derived from any microorganism including members of the genus *Arthrobacter*, *Arthrobacter* sp. S34 (deposited under accession no. FERM BP-6450), or mutants thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Applicants' arguments filed 06/13/2005 have been fully considered but they are not persuasive. Applicants' argue that following the analysis of Example 14 in the USPTO's "Synopsis of Application of Written Description Guidelines" and applying this example to the claimed invention supports applicants' position that the claimed invention is enabled by the specification. The Examiner respectfully disagrees since this example is not appropriate for determining whether the claimed invention meets the enablement requirement. The example in the USPTO's "Synopsis of Application of Written Description Guidelines" is provided only to determine whether claims meet the written description requirement of 35 U.S.C. 112, first paragraph.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any purified non-reducing saccharide-forming enzyme comprising an amino acid sequence that is at least 80% identical to SEQ ID NO: 1 which forms a non-reducing saccharide having a trehalose structure as an end unit from a reducing partial starch hydrolysate, where such enzyme is derived from any microorganism including members of the genus *Arthrobacter*, *Arthrobacter* sp. S34 (deposited under accession no. FERM BP-6450), or mutants thereof.

In order to meet the enablement requirement, one skilled in the art must be able to make and/or use the claimed invention without undue experimentation using the specification coupled with information known in the art. However, neither the specification nor the general knowledge of those skilled in the art provide guidance or prediction on making the claimed invention without undue experimentation.

The specification provides guidance and examples for isolating a non-reducing saccharide-forming enzyme from *Arthrobacter* sp. S34 (FERM BP-6450) that consists of the amino acid sequence of SEQ ID NO: 1, where said enzyme forms a non-reducing saccharide having a trehalose structure as an end unit from a reducing partial starch hydrolysate. The Sequence Listing shows that SEQ ID NO: 1 consists of 756 amino acid residues. Thus, to have at least 80% identity to SEQ ID NO: 1, at least 151 amino acid residues of SEQ ID NO: 1 must be different (e.g., amino acid deletion, insertion, addition, substitution, and combinations thereof).

However, the specification has not provided guidance and prediction as to the specific amino acid residues that can be changed without affecting enzyme activity nor has the specification provided guidance and prediction for specific amino acid residues that cannot be

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changed. Furthermore, the specification has not provided guidance and prediction for the biological sources that contain the claimed enzyme having at least 80% sequence identity to SEQ ID NO: 1.

In absence of such guidance and prediction, one of ordinary skill in the art must perform an enormous amount experimentation to search and screen for the amino acid residues that can be changed and yet still retain enzyme activity, and search and screen for the biological sources that contain the claimed invention. General teachings for screening and searching for the claimed invention is not guidance for making the claimed invention. Thus, the amount of experimentation to make the claimed invention is undue and outside the scope of routine experimentation.

6. Claims 69 and 70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The microorganism *Arthrobacter* sp. S34 (FERM BP-6450) is required to practice the claimed invention. The microorganism must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise known and readily available to the public. It is not apparent if the *Arthrobacter* sp. S34 (FERM BP-6450) or source materials to make *Arthrobacter* sp. S34 (FERM BP-6450) are both known and readily available to the public.

Applicants' referral to a deposit receipt on the amendment dated 01/23/2002 is noted, but is considered insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met since there is no indication in the specification as to public availability.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicant, or a statement by an attorney of record over his/her signature and registration number, stating that the specific microorganism has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of the patent, would satisfy the deposit requirement made herein.

### ***Conclusion***

7. No claims are allowed.

8. Claims 60-64 are objected to as being dependent upon a rejected base claim, but would be

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allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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